K030422

APR 1 4 2003

510(K) Summary
as required by 21 CFR section 807.92
for LiNA-BAG
Prepared February 7, 2003

Submitted by:	LiNA Medical CML ApS Formervangen 5 Glostrup Denmark DK-2600
Contact Person:	Mr. Niels Kornerup, President
Device Trade Name:	LiNA-Bag
Common Name:	Laparoscopic Specimen Retrieval Device
Classification:	Laparoscopic, General & Plastic Surgery, 876.1500 Class II
Predicate Devices:	Patton Endo-bag (K0122150), distributed by Patton Medical, 1000 Westbank Drive, Suite 5A200, Austin, TX 78746 ENDOPOUCH Specimen Retrieval Bag (K933104), manufactured by Ethicon, Inc., P.O. Box 151, Somerville, NJ 08876 Auto Suture ENDO CATCH Single Use Specimen Pouch (K922123), manufactured by U.S. Surgical, Division of TYCO, 150 Glover Ave., Norwalk, CT 06856

Description of Device:

The LiNA-Bag is a laparoscopic instrument consisting of a collapsible pouch attached and placed within a long slender multi-part tube allowing for introduction of said pouch through a laparoscopic trocar. Opening and closing of the pouch is activated by manual manipulation in a push and pull motion of the attached tube that has a corresponding nylon drawstring attached to the pouch.

Intended Use of Device:

The LiNA-Bag is a sterile, single-use bag designed to contain tissue, small organs and organic matter temporarily in order to facilitate the removal of this matter without wound contamination during laparoscopic procedures.

Substantial Equivalence to Predicate Device:

The LiNA-Bag is substantially equivalent to the Patton Endo-bag (K0122150), distributed by Patton Medical, 1000 Westbank Drive, Suite 5A200, Austin, TX 78746 and the ENDOPOUCH Specimen Retrieval Bag (K933104), manufactured by Ethicon, Inc., P.O. Box 151, Somerville, NJ 08876 and the Auto Suture ENDO CATCH Single Use Specimen Pouch (K922123), manufactured by U.S. Surgical, Division of TYCO, 150 Glover Ave, Norwalk, CT 06856.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2003

Mr. Niels Kornerup
President
LiNa Medical CML ApS
Formervangen 5
Glostrup, Denmark DK-2600

Re: K030422
Trade/Device Name: LiNa-Bag
Regulation Number: 21 CFR 876.1500
Regulation Names: Endoscope and accessories
Regulatory Class: II
Product Codes: GCJ
Dated: February 7, 2003
Received: February 10, 2003

Dear Mr. Kornerup:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

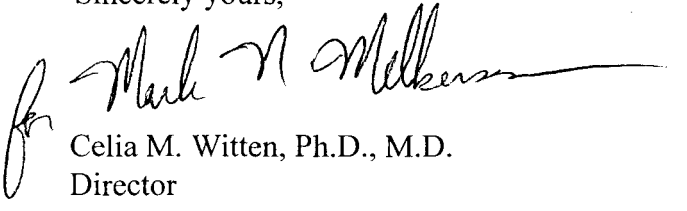
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030422

Device Name: LiNA-Bag, model LB-60 & LB-100

Indications for Use:

A single use retrieval bag designed to temporarily contain organs or stones and facilitate their removal from the patient without contamination during laparoscopic surgery such as the appendix, an ectopic pregnancy, gallbladder, gallstones, lymph nodes, ovaries, fibroid tumors, small sections of bowel and other tissue structures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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